

## R E M A R K S

The office action of January 21, 2009 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 10 through 18 remain in this case, claims 10 through 13 being amended by this response. No new matter has been added. More specifically, the amendments are fully supported by the application as filed, for example on page 16, lines 23-25, page 17, lines 12 through page 18, lines 3-21 and Figure 2.

The numbered paragraphs below correspond to the numbered paragraphs in the Office Action.

### **Rejection under 35 U.S.C. §101**

1. Claims 10-13 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10-13 have been amended to overcome this rejection. More specifically, claims 10-13 have been amended to include the language “are adapted to” as suggested by the Examiner. Reconsideration and withdrawal of the rejection of claims 10-13 are respectfully requested.

### **Rejection under 35 U.S.C. §112**

3. Claims 10-13 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-13 have been amended to overcome this rejection. More specifically, anode and cathode have been further defined in these claims. Accordingly, these terms in the claims should now be clear.

Applicant believes that these amendments have fully addressed the Examiner's rejections, and the claims are now in condition for allowance. Reconsideration and withdrawal of the rejection are respectfully requested.

### **Rejection under 35 U.S.C. §103**

5. Claims 10-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (3,943,936) in view of Heller (6,294,281). Applicant respectfully disagrees with this rejection.

As amended, claims 10-13 include, in part, “wherein the control unit includes a stimulation timing determining means that decides the timing of stimulation to generate control signals, and a stimulation timing changing means that changes the timing of stimulation to generate control signals; wherein the control unit changes the stimulation timing when certain conditions are fulfilled.”

Neither Rasor et al. nor Heller teach or suggest a change in stimulation timing triggered by the fulfillment of certain conditions.

The Examiner points to the following passage to support his statement that “Rasor discloses that the control unit comprises a stimulation timing determining means (“pulse forming circuit”) that decides the timing of pulses and a stimulation timing changing means (col. 11, lines 15-18) that changes the timing of simulation when certain conditions are met.” (present office action dated January 21, 2009, page 3, lines 21-24): “For demand pacing, the surface electrode 32 may be used to pick up the ventricle pulse and suppress the trigger circuit in the manner taught for example by Keller U.S. Pat. No. 3,431,912 or Greatbatch U.S. Pat. No. 3,478,746.” (col. 11, lines 15-18).

This passage merely states that a surface electrode 32 may be used to pick up the ventricular activity and suppress the trigger circuit. This passage does not teach or suggest any type of simulation timing changing means that is able to change the timing of simulation to generate control signals, where the control unit changes the stimulation timing when certain conditions are fulfilled.

The control of the stimulating timing of a pacemaker in the present invention is characterized in changing not only by the ventricular activity but also by the stimulation timing under certain conditions (information sent from outside, electrocardiographic information and the combination thereof). Therefore, there is an important difference between the present invention described in claims 10-13 and the invention of Rasor.

The present invention has the following advantages due to this difference. The stimulating timing of the present invention can be changed not only by the ventricular activity but also by fulfilling certain conditions of a patient. The changes in the stimulation timing triggered by detecting certain conditions of a patient make it possible to stimulate the patient's heart adequately without adjusting the patient's pacemaker. Furthermore, a plurality of ultra miniature pacemakers may be utilized all together by respectively changing their stimulation timings. Briefly, a plurality of ultra miniature pacemakers may optimally stimulate patient hearts by transmitting the information between pacemakers.

Amended claims 10-13 also include, in part, "wherein the biological fuel cell comprises an anode and a cathode; wherein the anode comprises an anode electrode and an immobile layer formed on a surface of the anode electrode by immobilization of mediators and oxidative enzymes for biological fuels, wherein said immobile layer prevents oxygen existing in a biological body from contacting said anode electrode; wherein the cathode comprises a cathode electrode and a coating material formed on the surface of the cathode electrode, wherein said coating material is capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions." These features efficiently promote reaction at the anode and the cathode.

Neither Rasor et al. or Heller teach or suggest an immobile layer on the anode electrode that prevents oxygen existing in a biological body from contacting the anode electrode. In addition, neither Rasor et al. nor Heller teach or suggest a coating on a surface of a cathode electrode that prevents permeation of the reactive substances and allows permeation of oxygen and hydrogen ions.

In addition, the biological fuel cell disclosed in Heller was not designed with safety considerations in mind. In contrast, the structural materials of the present invention are carefully selected to maximize safety in the human body. The invention in Heller has to inevitably include a waste container of products (even reactant or fuel may be provided directly from body fluid), because materials safe for use in the human body are not necessarily utilized (as indicated in previous office action response). Furthermore, the structure of the biological fuel in Heller faces a difficult problem. As pacemakers are used for a long period (typically more than 10 years), the

biological fuel cell in Heller must include a relatively large waste container. However, the size of the attached waste container is unrealistic even for the actual usage of the conventional pacemaker. In addition, it is impossible to add a reservoir to an ultra miniature pacemaker that is designed to attach to a tip of catheter for implanting in a heart.

In contrast, the structural materials of the present invention are carefully selected with human safety considerations in mind, so that the fuel (such as glucose, oxygen) used in the present invention may be provided directly from blood or body fluid, and reactants may be discharged as it is into the blood or the body fluid.

The biological fuel cell of the present invention has only an anode and a cathode electrode, and does not need a container for fuels or waste products in addition to the biological fuel cell. Therefore, the biological fuel cell of the present invention may be in ultra miniature in size (capable of attaching the pacemaker to a tip of a catheter) and operable for a long period (more than a few years) by providing the fuels from body fluid and discharging the products into the body. As a result, an “open-type” (i.e., non self-contained) fuel cell including an anode and a cathode without containers is achieved.

With respect to Reichert (5,270,128), Reichert does not teach or suggest a biological fuel cell with the combination of elements in claims 10-13 or anything about safety for use in the human body.

Amended claims 10-13 also include, in part, “wherein said anode and said cathode are adapted to contact the electrolyte solution”.

As the Examiner acknowledges, Rasor et al. does not teach a biological fuel cell. Heller teaches a biological fuel cell that includes various artificial compounds as mediators containing elements including osmium, ruthenium and ferrocene, which may threaten safety when they are in contact with blood or body fluid due to their toxicity or pro-allergic properties.

In claims 10-13, the anode and the cathode are adapted to contact the electrolyte solution, which is made up of blood and/or body fluid. The invention described in claims 10-13 of the present application is preferably fabricated exclusively from compounds derived from biologic organs except inert metals or graphite.

Heller teaches away from an anode and a cathode adapted to contact blood or body fluid, because the biological fuel cell that Heller uses would threaten the health and safety of the recipient if the anode or the cathode of the biological fuel cell were in contact with blood or body fluid. The mediators taught in Heller cannot be applied to the present invention because of their potential risk to a human body.

Reichert also does not teach or suggest an anode or a cathode of a biological fuel cell adapted to contact blood or body fluid.

In addition, the ultra miniature integrated cardiac pacemaker of claims 11–13 make it possible to synchronize external devices such as other cardiac pacemakers with the cardiac pacemaker of the present invention with ways to communicate information between them.

Since claims 10-13 include multiple elements not taught or suggested in Rasor et al., Heller, or Reichert, alone or in combination, claims 10-13 are not obvious over these references. Reconsideration and withdrawal of the rejection of claims 10-13 are respectfully requested.

### **Conclusion**

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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